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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,196	09/22/2000	Stephen James Russell	18093/1130	9873

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FISH & RICHARDSON P.C.  
3300 DAIN RASCHER PLAZA  
60 SOUTH SIXTH STREET  
MINNEAPOLIS, MN 55402

EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/668,196	RUSSELL ET AL.
	Examiner Zachariah Lucas	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 December 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7, 9, 11-22, 24, 26 and 28-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7, 9, 11-22, 24, 26, 28-33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

<p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.</p>	<p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____.</p>
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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-7, 9,11-22,24,26,28-33 are pending and under consideration in the present action.
2. The rejections of record are being maintained in a restated form in which two additional references have been added to support the obviousness rejection. The arguments presented by the applicant in the response filed December 23, 2002 will be addressed below.
3. The finality of the prior action is being withdrawn. However, because the references being added to the discussion of the 103 rejection (Taqi et al, The Lancet, May 16, 1981:1112; and Bluming et al., The Lancet, July 10, 1971: 105-106) were submitted by the applicant in the IDS filed January 5, 2001, the rejection is being made final.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1-3 and 23 were rejected in the prior actions under 35 U.S.C. 103(a) as being unpatentable over either Bateman et al. (Gene Therapy 6, Supp. 1, abstract 24- the Bateman abstract) or Lindarkis et al. (Gene Therapy, 6, Supp. 1, abstract 13- Lindarkis). These rejections are withdrawn. Although the references clearly suggest that the genes of certain measles proteins

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may be injected into tumor cells using viral vectors, they do not, without more, point to the use of attenuated measles virus.

6. Claims 1-7, 9, 11-22, 24, and 28-33 were rejected in the prior actions under 35 U.S.C. 103(a) as obvious over Bateman et al (Cancer Research 60:1492-1497- the Bateman article) in view of Wiebel et al. (Arch. Dis. Childhood 48:532-536 1973). This rejection is maintained for the reasons of record, further in light of the teachings and suggestions of Lindarkis, the Bateman abstract, Taqi, and Bluming. The applicant traverses the rejection of these claims on two grounds in the response filed on December 23, 2002. First, the applicant argues that the Examiner has not established a *prima facie* case of obviousness on these claims by indicating that the examiner has not shown all of the limitation s of the claimed invention. More particularly, the applicant argues that there is not suggestion or motivation in the prior art to lead one skilled in the art to attenuated measles virus to reduce the number of tumor cells in a mammal.

As described in the prior actions, the Bateman article teaches the administration of polynucleotides encoding measles virus proteins as a method of reducing the number of cancer cells in a mammal. The prior action also points out that the main difference between the claimed invention and the prior art is that the claimed invention uses attenuated measles virus as a vector rather than the plasmids used in the Bateman article. Wiebel teaches an attenuated measles virus in a vaccine composition. From the Bateman article, it is clear that what is important to the treatment is the insertion of the measles virus DNA into the tumor cells to be killed. The plasmids used in the reference were just a convenient vector. This was highlighted by the teachings of both Lindarkis and the Bateman abstract, which suggest the use of viral vectors to

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introduce the DNA into cells. Thus, it would be obvious to one of ordinary skill in the art to use the attenuated measles virus taught by Weibel as a convenient vector for the measles virus DNA.

One of ordinary skill in the art would have had a reasonable expectation of success due to the suggestions in the art of the use of viral vectors for the introduction of the measles virus DNA. Further, the art also has examples of live measles virus as effective in causing the regression of cancers. See Taqi and Bluming. From these additional references, one of ordinary skill in the art would have had further grounds for believing that the use of an attenuated measles virus as a vector would have no effect on the operability of the measles virus DNA to destroy cancer cells. As both the whole virus and the isolated DNA have been shown to reduce tumors, there would be no reason for one of ordinary skill in the art to expect anything but success in the use of an attenuated virus as a vector for the DNA. For the reasons stated above in conjunction with the reasons of record, the applicant's argument that a *prima facie* case for obviousness has not been made is not found persuasive.

The second grounds for traversal of the rejection is that, even if the examiner had made a *prima facie* case for obviousness, there is objective evidence of non-obviousness tending to counter the *prima facie* case. The examiner is not persuaded by the applicant's argument. The applicant argues both surprising results and that there has been a long felt need in the art for the treatment of cancers. With regards to the surprising results argument, the examiner would direct attention to the Taqi, Bluming, and Lindarkis and Bateman references- all of which provide evidence that the "surprising" effect of administration of the measles virus was either known, or clearly indicated, in the art. The fact that the applicant took the additional step of using the

attenuated virus does not overcome the effect of these teachings. Further, the effect of the administration of attenuated virus was not a surprising result as demonstrated above.

The argument that the applicant's discovery has met a long felt but unfulfilled need in the art is also found unpersuasive. While the examiner agrees wholeheartedly that there has been, and continues to be a need for treatments effective in fighting off cancers, the examiner does not see the nexus between this need and the applicants claimed invention. The applicant points out, and the examiner agrees, that long felt need is counted from when the need arose, not from the date of the closest prior art. However, a long felt need alone is not sufficient to overcome obviousness.

Along with the long felt need, some other factor is required that makes the need relevant to the patentability of the claimed invention. See e.g. MPEP § 716.01 (b) (discussing the need for a nexus between the secondary consideration and the claimed subject matter). Such a nexus could be established, for example, by showing that the need, although felt, was not recognized, or that although the need was felt, others had tried and failed to solve the problem without success in manner relevant to the claimed invention. See e.g., Chisum et al., *Principles of Patent Law*, 1998, pages 628-630 (discussion of relevance of long felt need and failure of others to patentability). In the present case, no such nexus has been demonstrated. The need for treatments has been known, and although others have failed, still others have succeeded. Of more relevance is the fact that the Bateman and Lindarkis had succeeded in a manner highly relevant to the presently claimed invention. Thus, the applicant has not made a persuasive argument showing objective evidence of nonobviousness. As the examiner also believes that a *prima facie* case of obviousness has been met, the rejection is maintained.

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7. The applicant arguments traversing the remaining rejections are based upon the inadequacy of the "primary references" in teaching the use of the attenuated measles virus to reduce the number of viable cancer cells in a mammal. The examiner feels that this issue has been adequately discussed above. Therefore, the remaining outstanding obviousness rejections are maintained for the reasons above in combination with the reasons of record.

***Conclusion***

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
January 7, 2003

  
JAMES C. HOUSEL 1/13/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600